Inventors: Gerber, Starkebaum and Swoyer

Docket No.: P-11611.00

CLAIMS:

A method for treating fecal incontinence comprising:
 implanting a bulking prosthesis in tissue proximate to an anal sphincter,
 wherein the bulking prosthesis is in a miniature state at the time of implantation and
 assumes an enlarged state after implantation.

- 2. The method of claim 1, wherein the tissue comprises at least one of a submucosa and a musculature underlying the submucosa.
- 3. The method of claim 1, wherein implanting the bulking prosthesis comprises: penetrating a mucosa proximate to the tissue with a syringe needle; and implanting the bulking prosthesis in the tissue through the syringe needle.
- 4. The method of claim 1, wherein implanting the bulking prosthesis comprises: drawing a mucosa away from a musculature underlying a submucosa; forming a pocket in one of the submucosa and the musculature; and implanting the bulking prosthesis in pocket.
- 5. The method of claim 4, wherein drawing the mucosa away from musculature underlying the submucosa comprises applying vacuum pressure to an instrument proximate to the mucosa.
- 6. The method of claim 4,
 wherein forming a pocket in one of the submucosa and the musculature comprises
 inserting a needle through mucosa, thereby forming a hole in the mucosa, and
 implanting the bulking prosthesis in the tissue through the hole.
- 7. The method of claim 1, wherein the bulking prosthesis comprises a hydrogel.

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8. The method of claim 1, wherein the bulking prosthesis comprises a material that

absorbs fluid from the tissue to assume the enlarged state.

9. A system comprising:

a needle to make a hole through a mucosa proximate to an anal sphincter;

a tubular instrument having a distal end and an opening at the distal end; and

a pushing agent to push a bulking prosthesis through the tubular instrument and

through the hole in the mucosa.

10. The system of claim 9, further comprising:

a source of vacuum pressure; and

a conduit to deliver the vacuum pressure from the source to the mucosa.

11. The system of claim 10, wherein the conduit comprises a distal end with a cavity at

the distal end to receive the mucosa when the cavity is positioned proximate to the mucosa

and the vacuum pressure is delivered to the mucosa.

12. The system of claim 9, wherein the tubular instrument comprises the needle.

13. A device comprising:

a bulking prosthesis in the shape of a partial cylinder having an inner radius,

wherein the bulking prosthesis comprises a hydrophilic polymer that forms a

hydrogel in the presence of water, and

wherein the inner radius of the partial cylinder is sized to conform to close the anus of

a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial

with the anus of the patient and when the patient exercises voluntary control over an external

sphincter.

14. The device of claim 13, wherein the bulking prosthesis has a substantially half-

cylinder shape.

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15. The device of claim 13, wherein the bulking prosthesis assumes one of a miniature state and an enlarged state, and the prosthesis assumes the shape of the partial cylinder in the enlarged state.

16. The device of claim 13, further comprising a Dacron mesh surrounding the hydrophilic polymer.

17. The device of claim 13, further comprising a radiopaque material.

18. A device comprising:

a rod-like bulking prosthesis having a sharpened tip,

wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water.

19. The device of claim 18, wherein the sharpened tip comprised at least one of a conical tip, a needle-like tip and a wedge-shaped tip.

20. The device of claim 18, further comprising a helical thread around the rod-like bulking prosthesis.

21. The device of claim 18, wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water, and wherein the rod-like bulking prosthesis has a length of at least four millimeters when in the enlarged state.

22. A method for manufacturing a bulking prosthesis comprising:

providing a rod-like bulking prosthesis that comprises a hydrophilic polymer that
forms a hydrogel in the presence of water; and
forming a sharpened tip on an end of the bulking prosthesis.

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23. The method of claim 22, further comprising forming a slot in the bulking prosthesis.

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24. The method of claim 22, further comprising machining a helical thread around the bulking prosthesis.

25. A method for implanting a bulking prosthesis comprising: implanting a rod-like bulking prosthesis having a sharpened tip proximate to an anal

sphincter, the bulking prosthesis engaged with an application device; and withdrawing the application device.

26. The method of claim 25, further comprising disengaging the bulking prosthesis from application device.

27. The method of claim 25, further comprising rotating the bulking prosthesis with the application device.